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10/734,059	12/10/2003	Michael A. Centanni	ST8613US	8624

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EXAMINER	
CHORBAJI, MONZER R	
ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,059	CENTANNI, MICHAEL A.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/6/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This final action is in response to the amendment received on 05/18/2007

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 18-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure does not teach that the steps of generating ozone gas and introducing vaporized hydrogen peroxide are applied in alternating and contemporaneous manners.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 17-20, 22-23, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pai et al (U.S.P.N. 6,156,267) in view of Childers (WO 97/47331) and Kazi et al (U.S.P.N. 5,578,280).

Regarding claim 17, Pai teaches a method for deactivation using at least one vaporous or gaseous chemical (5-12) where conventional sterilants (col.4, lines 50-54) such as vaporized hydrogen peroxide and ozone (col.7, line 67 and col.8, lines 1-3) are combined. One of ordinary skill in the art upon reading Pai would recognize that sources for generating vaporized hydrogen peroxide and ozone are parts of the teachings of this reference. Pai fails to teach that his sterilization system includes recirculating the generated sterilants; a removing moisture step by using a dryer; and a vapor hydrogen peroxide destroying step.

Childers recirculates vapor hydrogen peroxide (figure 6:18) in combination with a carrier gas (page 7, lines 24-26) through a closed loop (see the directional arrows in figure 6) conduit (the conduit is considered made up of parts16, 34, and 36 in figure 7) in communication (figure 6:12 and 14) with a region (figure 7:10) at an inlet of the region (figure 7:12) and at an outlet of the region (figure 7:14) by a blower disposed within the region (figure 7:22a), so that superior kill potentials and more efficient sterilization is obtained by partially and selectively drying the carrier gas in response to the sterilization parameters (page 5, lines 25-37). Childers teaches the following: removing moisture from the gas (page 9, lines 17-18) circulating in the conduit (figure 7:16, 34, and 36),

wherein the moisture is removed by a drying means (figure 7:28) disposed in the conduit (figure 7:16, 34, and 36); introducing vaporized hydrogen peroxide into the conduit (figure 7:18, 16, 34, and 36), where the vaporized hydrogen peroxide is produced by a vaporizer (figure 7:18) disposed within the conduit (figure 7:18, 16, 34, and 36); and destroying vaporized hydrogen peroxide removed from the region through the outlet (figure 7:12, 10, 14, and 20), wherein the vaporized hydrogen peroxide is destroyed by a destroyer disposed in the conduit (page 8, lines 13-19). As to the limitation of introducing vaporized hydrogen peroxide downstream of the ozone generator, Childers places the vaporizer (figure 7:18) just before the inlet port into the region such that one of ordinary skill in the art would recognize that Childers intent is to introduce vapor hydrogen peroxide as the last input into the circulating gas entering the region (figure 7:18, 12, and 10). As such other agents are introduced into the circulating gas upstream from the vaporizer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method in Pai with the sterilant/carrier gas recirculating closed loop system, because superior kill potentials and more efficient sterilization is obtained by partially and selectively drying the carrier gas in response to the sterilization parameters as explained by Childers (page 5, lines 25-37).

Pai and Childers fail to teach producing ozone gas from the circulating gas and placing the drying means upstream from the ozone generator. Kazi produces ozone (figure 7:63, 84, and 66) in a circulating air loop system (figure 7:80, 60 and col.17, lines 30-34) using the circulating gas (col.17, lines 31-34), because it results in producing

ozone with high concentration over a shorter period of time when compared to other ozone generators (col.17, lines 35-42). Kazi further teaches that the air entering the ozone generator must be first filtered and dried (col.14, lines 49-50) in order to prevent reducing the efficiency of the ozone generator (col.14, lines 55-56). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Pai/Childers with the air mixture circulating ozone generator, because such a generator results in the efficient production of ozone with high concentration over a shorter period of time in comparison to other ozone generators as explained b y Kazi (col.17, lines 35-42 and col.14, lines 55-56).

As to claims 18-19, Pai combines vaporized hydrogen peroxide and ozone (col.7, line 67 and col.8, lines 1-3) where multiple sensors are used to insure that the concentration of each sterilant is maintained within certain sterilization ranges such that one of ordinary skill in the art would recognize that as the concentrations of hydrogen peroxide and ozone deviate from their target values, additions of each sterilant would require occurring either at the same time (for example, sudden large drop in the concentration of both sterilants) and/or in an alternate pattern (for example, the concentration of one sterilant is more stable than the other). Also, one of ordinary skill in the art will recognize that depending on the conditions of a sterilization cycle, the concentration of one sterilant may change while the concentration of other remains within the target range so that only modification of the concentration of one sterilant is required this case.

Regarding claim 20, Pai and Childers fail to teach producing ozone gas from the circulating gas using an electrical discharge. Kazi produces ozone (figure 7:63, 84, and 66) using a corona discharge apparatus (figure 1:1) in a circulating air loop system (figure 7:80, 60, 63, 84, 66, and col.17, lines 30-34) using the circulating gas (col.17, lines 31-34), because it results in producing ozone with high concentration over a shorter period of time when compared to other ozone generators (col.17, lines 35-42). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Pai/Childers with the air mixture circulating ozone generator, because such a generator results in the efficient production of ozone with high concentration over a shorter period of time in comparison to other ozone generators as explained b y Kazi (col.17, lines 35-42 and col.14, lines 55-56).

Regarding claim 22, Pai and Childers fail to teach monitoring the concentration of ozone gas. Kazi produces ozone (figure 7:63, 84, and 66) in a circulating air loop system (figure 7:80, 60, 63, 84, 66, and col.17, lines 30-34) where the concentration of ozone in the final produced mixture is increased (col.16, lines 26-29) .One of ordinary skill in the art would, upon reading the Kazi reference, recognizes that Kazi monitors the concentration of the generated ozone in order to ascertain the amount of ozone increase in the produced gaseous sterilant. It would have been obvious to one of ordinary skill in the art at the time of the invention to monitor the concentration of ozone in the modified method in Pai/Childers/Kazi in order to determine when the concentration of ozone was sufficient to sterilize.

Regarding claim 23, Pai combines vaporized hydrogen peroxide and ozone (col.7, line 67 and col.8, lines 1-3) where multiple sensors are used to insure that the concentration of each sterilant is maintained within certain sterilization ranges. One of ordinary skill in the art would recognize that as the concentrations of hydrogen peroxide and ozone deviate from their target values during sterilization cycles, additions (modification) of the generated sterilants are required to maintain the concentrations of the sterilants within the target ranges.

Regarding claims 25-26 and 28, Pai fails to teach that the sterilization system includes heating the recirculating gas that includes air and destroying vapor hydrogen peroxide. Childers heats the recirculating gas that includes air (figure 7:58a, 58b, 18, and page 5, lines 10-11) in order to control the temperature of the carrier gas entering the vaporizer (page 8, lines 34-37). Childers also destroys vapor hydrogen peroxide (figure 7:20 and page 8, lines 15-19) so that vapor hydrogen peroxide is decomposed to water and oxygen. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method in Pai by heating the recirculating gas that includes air and destroying vapor hydrogen peroxide in order to control the temperature of the carrier gas entering the vaporizer and provide water and oxygen as products for disposal.

Regarding claim 27, both Pai and Childers fail to teach using a desiccant to remove moisture. Kazi teaches that the air entering the ozone generator must be first filtered and dried (col.14, lines 49-50) using a desiccating liquid (col.16, line 49) in order to prevent reducing the efficiency of the ozone generator (col.14, lines 55-56). It would

have been obvious to one of ordinary skill in the art at the time of the invention to modify the method in Pai/Childers by using a desiccant to remove moisture in order to prevent reducing the efficiency of the ozone generator

6. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pai et al (U.S.P.N. 6,156,267) in view of Childers (WO 97/47331) and Kazi et al (U.S.P.N. 5,578,280) as applied to claim 17 and further in view of Bell et al (U.S.P.N. 5,516,493).

Pai, Childers, and Kazi fail to teach that using ultraviolet light leads to producing ozone. Bell generates ozone and further teaches that ultraviolet light contribute to ozone formation (col.7, lines 1-2). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified method in Pai/Childers/Kazi with the ultraviolet source since ultraviolet light enhances the production of ozone as explained by Bell (col.7, lines 5-7).

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pai et al (U.S.P.N. 6,156,267) in view of Childers (WO 97/47331), Kazi et al (U.S.P.N. 5,578,280) as applied to claim 17 and further in view of Karlson (U.S.P.N. 5,069,880).

Pai, Childers, and Kazi fail to teach disposing an ozone destroyer in a supplemental conduit fluidly connected with the conduit downstream of the region. Karlson places an ozone destroyer (figure 8:W) in a supplemental conduit (unlabeled line connecting the top of tank B with destroyer W through valve L in figure 8) since with such a system the destroyer controls the generation of ozone by monitoring its temperature (col.7, lines 63-66). It would have been obvious to one of ordinary skill in

the art at the time of the invention to provide the modified method in Pai/Childers/Kazi with the ozone destroyer placed in a supplemental conduit, since with such a system the destroyer controls the generation of ozone by monitoring its temperature as explained by Karlson (col.7, lines 63-66).

Response to Arguments

8. Applicant's arguments see pages 6-9 of the Remarks section, filed on 05/18/2007, with respect to the rejection(s) of claim(s) 17-28 under Pai in view of Childers have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view Pai and Childers in view of Kazi.

On page 7 of the Remarks section, Applicant argues that Childers provides a bypass line 36 to allow a portion of the carrier gas to bypass dryer 28, thereby maintaining the moisture in the bypassed carrier gas where in contrast, all of the gas circulating through applicant's closed loop system has moisture removed therefrom prior to ozone gas generation.

It is noted that the instant claims do not require that all of the circulating gas to pass through the dryer as applicant argues.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571)272-1271. The examiner can normally be reached on M-F 9:00-5:30.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

/M. R. C./